

Exhibit L

Initial Shared System REMS approval: 04/2019

Most Recent Modification: 01/2023

Mifepristone Tablets, 200 mg

Progestin Antagonist

**RISK EVALUATION AND MITIGATION STRATEGY (REMS)
SINGLE SHARED SYSTEM FOR MIFEPRISTONE 200 MG**

I. GOAL

The goal of the REMS for mifepristone is to mitigate the risk of serious complications associated with mifepristone by:

- a) Requiring healthcare providers who prescribe mifepristone to be certified in the Mifepristone REMS Program.
- b) Ensuring that mifepristone is only dispensed by or under the supervision of certified prescribers, or by certified pharmacies on prescriptions issued by certified prescribers.
- c) Informing patients about the risk of serious complications associated with mifepristone.

II. REMS ELEMENTS

A. Elements to Assure Safe Use

1. Healthcare providers who prescribe mifepristone must be specially certified.
 - a. To become specially certified to prescribe mifepristone, healthcare providers must:
 - i. Review the Prescribing Information for mifepristone.
 - ii. Complete a *Prescriber Agreement Form*. By signing¹ a *Prescriber Agreement Form*, prescribers agree that:
 - 1) They have the following qualifications:
 - a) Ability to assess the duration of pregnancy accurately
 - b) Ability to diagnose ectopic pregnancies
 - c) Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary
 - 2) They will follow the guidelines for use of mifepristone (see b.i-vii below).
 - b. As a condition of certification, prescribers must follow the guidelines for use of mifepristone described below:
 - i. Ensure that the *Patient Agreement Form* is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained. Ensure any questions the patient may have prior to receiving mifepristone are answered.
 - ii. Ensure that the healthcare provider and patient sign the *Patient Agreement Form*.

¹ In this REMS, the terms “sign” and “signature” include electronic signatures.

- iii. Ensure that the patient is provided with a copy of the *Patient Agreement Form* and Medication Guide.
 - iv. Ensure that the signed *Patient Agreement Form* is placed in the patient's medical record.
 - v. Ensure that any deaths are reported to the Mifepristone Sponsor that provided the mifepristone, identifying the patient by a non-identifiable reference and including the NDC and lot number from the package of mifepristone that was dispensed to the patient.
 - vi. If mifepristone will be dispensed by a certified pharmacy:
 - 1) Provide the certified pharmacy a signed *Prescriber Agreement Form*.
 - 2) Assess appropriateness of dispensing mifepristone when contacted by a certified pharmacy about patients who will receive mifepristone more than 4 calendar days after the prescription was received by the certified pharmacy.
 - 3) Obtain the NDC and lot number of the package of mifepristone the patient received in the event the prescriber becomes aware of the death of the patient.
 - vii. The certified prescriber who dispenses mifepristone or who supervises the dispensing of mifepristone must:
 - 1) Provide an authorized distributor with a signed *Prescriber Agreement Form*.
 - 2) Ensure that the NDC and lot number from each package of mifepristone dispensed are recorded in the patient's record.
 - 3) Ensure that healthcare providers under their supervision follow guidelines i.-v.
 - c. Mifepristone Sponsors must:
 - i. Ensure that healthcare providers who prescribe their mifepristone are specially certified in accordance with the requirements described above and de-certify healthcare providers who do not maintain compliance with certification requirements.
 - ii. Ensure prescribers previously certified in the Mifepristone REMS Program complete the new *Prescriber Agreement Form*:
 - 1) Within 120 days after approval of this modification, for those previously certified prescribers submitting prescriptions to certified pharmacies.
 - 2) Within one year after approval of this modification, if previously certified and ordering from an authorized distributor.
 - iii. Ensure that healthcare providers can complete the certification process by email or fax to an authorized distributor and/or certified pharmacy.
 - iv. Provide the Prescribing Information and their *Prescriber Agreement Form* to healthcare providers who inquire about how to become certified.
 - v. Ensure annually with each certified prescriber that their locations for receiving mifepristone are up to date.
- The following materials are part of the Mifepristone REMS Program:
- *Prescriber Agreement Form for Danco Laboratories, LLC*
 - *Prescriber Agreement Form for GenBioPro, Inc.*
 - *Patient Agreement Form*

2. Pharmacies that dispense mifepristone must be specially certified
 - a. To become specially certified to dispense mifepristone, pharmacies must:
 - i. Be able to receive *Prescriber Agreement Forms* by email and fax.
 - ii. Be able to ship mifepristone using a shipping service that provides tracking information.
 - iii. Designate an authorized representative to carry out the certification process on behalf of the pharmacy.
 - iv. Ensure the authorized representative oversees implementation and compliance with the Mifepristone REMS Program by doing the following:
 - 1) Review the Prescribing Information for mifepristone.
 - 2) Complete a *Pharmacy Agreement Form*. By signing a *Pharmacy Agreement Form*, the authorized representative agrees that the pharmacy will put processes and procedures in place to ensure the following requirements are completed:
 - a) Verify that the prescriber is certified by confirming their completed *Prescriber Agreement Form* was received with the prescription or is on file with the pharmacy.
 - b) Dispense mifepristone such that it is delivered to the patient within 4 calendar days of the date the pharmacy receives the prescription, except as provided in c) below.
 - c) Confirm with the prescriber the appropriateness of dispensing mifepristone for patients who will receive the drug more than 4 calendar days after the date the pharmacy receives the prescription and document the prescriber's decision.
 - d) Record in the patient's record the NDC and lot number from each package of mifepristone dispensed.
 - e) Track and verify receipt of each shipment of mifepristone.
 - f) Dispense mifepristone in its package as supplied by the Mifepristone Sponsor.
 - g) Report any patient deaths to the prescriber, including the NDC and lot number from the package of mifepristone dispensed to the patient, and remind the prescriber of their obligation to report the deaths to the Mifepristone Sponsor that provided the mifepristone. Notify the Mifepristone Sponsor that provided the dispensed mifepristone that the pharmacy submitted a report of death to the prescriber, including the name and contact information for the prescriber and the NDC and lot number of the dispensed product.
 - h) Not distribute, transfer, loan or sell mifepristone except to certified prescribers or other locations of the pharmacy.
 - i) Maintain records of *Prescriber Agreement Forms*.
 - j) Maintain records of dispensing and shipping.
 - k) Maintain records of all processes and procedures including compliance with those processes and procedures.
 - l) Maintain the identity of the patient and prescriber as confidential, including limiting access to patient and prescriber identity only to those personnel necessary to dispense mifepristone in accordance with the Mifepristone REMS Program requirements, or as necessary for payment and/or insurance purposes.
 - m) Train all relevant staff on the Mifepristone REMS Program requirements.

- n) Comply with audits carried out by the Mifepristone Sponsors or a third party acting on behalf of the Mifepristone Sponsors to ensure that all processes and procedures are in place and are being followed.
- b. Mifepristone Sponsors must:
 - i. Ensure that pharmacies are specially certified in accordance with the requirements described above and de-certify pharmacies that do not maintain compliance with certification requirements.
 - ii. Ensure that pharmacies can complete the certification process by email and fax to an authorized distributor.
 - i. Verify annually that the name and contact information for the pharmacy's authorized representative corresponds to that of the current designated authorized representative for the certified pharmacy, and if different, require the pharmacy to recertify with the new authorized representative.

The following materials are part of the Mifepristone REMS Program:

- *Pharmacy Agreement Form for Danco Laboratories, LLC*
 - *Pharmacy Agreement Form for GenBioPro, Inc.*
3. Mifepristone must be dispensed to patients with evidence or other documentation of safe use conditions as ensured by the certified prescriber in signing the *Prescriber Agreement Form*.
 - a. The patient must sign a *Patient Agreement Form* indicating that the patient has:
 - i. Received, read and been provided a copy of the *Patient Agreement Form*.
 - ii. Received counseling from the healthcare provider regarding the risk of serious complications associated with mifepristone.

B. Implementation System

1. Mifepristone Sponsors must ensure that their mifepristone is only distributed to certified prescribers and certified pharmacies by:
 - a. Ensuring that distributors who distribute their mifepristone comply with the program requirements for distributors.
 - i. The distributors must put processes and procedures in place to:
 - 1) Complete the certification process upon receipt of a *Prescriber Agreement Form* or *Pharmacy Agreement Form*.
 - 2) Notify healthcare providers and pharmacies when they have been certified by the Mifepristone REMS Program.
 - 3) Ship mifepristone only to certified pharmacies or locations identified by certified prescribers.
 - 4) Not ship mifepristone to pharmacies or prescribers who become de-certified from the Mifepristone REMS Program.
 - 5) Provide the Prescribing Information and their Prescriber Agreement Form to healthcare providers who (1) attempt to order mifepristone and are not yet certified, or (2) inquire about how to become certified.
 - ii. Put processes and procedures in place to maintain a distribution system that is secure,

confidential and follows all processes and procedures, including those for storage, handling, shipping, tracking package serial numbers, NDC and lot numbers, proof of delivery and controlled returns of mifepristone.

- iii. Train all relevant staff on the Mifepristone REMS Program requirements.
 - iv. Comply with audits by Mifepristone Sponsors or a third party acting on behalf of Mifepristone Sponsors to ensure that all processes and procedures are in place and are being followed for the Mifepristone REMS Program. In addition, distributors must maintain appropriate documentation and make it available for audits.
- b. Ensuring that distributors maintain secure and confidential distribution records of all shipments of mifepristone.
- 2. Mifepristone Sponsors must monitor their distribution data to ensure compliance with the Mifepristone REMS Program.
- 3. Mifepristone Sponsors must ensure that adequate records are maintained to demonstrate that the Mifepristone REMS Program requirements have been met, including, but not limited to records of mifepristone distribution; certification of prescribers and pharmacies; and audits of pharmacies and distributors. These records must be readily available for FDA inspections.
- 4. Mifepristone Sponsors must audit their new distributors within 90 calendar days and annually thereafter after the distributor is authorized to ensure that all processes and procedures are in place and functioning to support the requirements of the Mifepristone REMS Program. Mifepristone Sponsors will take steps to address their distributor compliance if noncompliance is identified.
- 5. Mifepristone Sponsors must audit their certified pharmacies within 180 calendar days after the pharmacy places its first order of mifepristone, and annually thereafter audit certified pharmacies that have ordered mifepristone in the previous 12 months, to ensure that all processes and procedures are in place and functioning to support the requirements of the Mifepristone REMS Program. Mifepristone Sponsors will take steps to address their pharmacy compliance if noncompliance is identified.
- 6. Mifepristone Sponsors must take reasonable steps to improve implementation of and compliance with the requirements of the Mifepristone REMS Program based on monitoring and assessment of the Mifepristone REMS Program.
- 7. Mifepristone Sponsors must report to FDA any death associated with mifepristone whether or not considered drug-related, as soon as possible but no later than 15 calendar days from the initial receipt of the information by the Mifepristone Sponsor. This requirement does not affect the sponsors' other reporting and follow-up requirements under FDA regulations.

C. Timetable for Submission of Assessments

The NDA Sponsor must submit REMS assessments to FDA one year from the date of the approval of the modified REMS (1/3/2023) and annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 90 calendar days before the submission date for that assessment. The NDA Sponsor must submit each assessment so that it will be received by the FDA on or before the due date.